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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/462,633 01/27/00 UKAI

K 423-54

EXAMINER

HM12/1105

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PULLIAM, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

11/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/462,633

Applicant(s)

UKAI ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/16/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Amendment B and the Corrected Filing Receipt, received August 16, 2001 and August 23, 2001, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-19, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/25066 to Depui *et al.*. Depui *et al.* teach of an oral pharmaceutical formulation comprising a proton pump inhibitor, combined with an alkaline substance, protected by coatings. Depui *et al.* disclose that examples of proton pump inhibitors are pantaprazole, lansoprazole, and omeprazole (p 8-11). Depui *et al.* also teach that acceptable alkaline substances can be sodium, potassium, calcium, and magnesium salts of phosphoric and carbonic acid, among others (p 15, l 1-5). In addition, Depui *et al.* give examples which include hydroxypropyl cellulose and crosslinked polyvinylpyrrolidone as core ingredients (p 29, l 23 and p 31, l 5). Depui *et al.* also teach that the core formulation will be coated with a separating layer, an enteric coating, and can have additional coatings.

Additionally, applicant's claim 26 claims the drug and excipient mixed in the core, which additional portions of the excipient coated on the outside. Example 4 of the reference teaches crospovidone present in both the core and the second coating layer. These teachings anticipate applicant's claims to a pharmaceutical composition comprising a benzimidazole and an additive (alkaline agent, hydroxypropyl cellulose, or crospovidone), with an intermediate layer, an enteric coating, and optional additional coatings.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-19, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui *et al.* as applied above. Depui *et al.* does not specifically teach all of the possible choices for component B in applicant's claimed composition. However, Depui *et al.* does teach the combination of a benzimidazole with an alkaline agent, such as sodium, potassium, calcium, and magnesium salts of phosphoric and carbonic acid, as well as crospovidone and hydroxypropyl cellulose (p 15, I 1-5). One of ordinary skill in the art would have been motivated to combine any well known alkaline substance with a benzimidazole, based on the teachings of Depui *et al.* in order to form a formulation for treatment of gastrointestinal disorders. Therefore, this invention

as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 21, 22, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui *et al.* as applied above, and further in view of US Patent 6,030,988 to Gilis *et al.*. Depui *et al.* is described above as teaching a formulation comprising a benzimidazole, combined with an alkaline agent or an excipient such as crospovidone or HPC, an intermediate coating, an enteric coating and optional additional coatings. Depui *et al.* does not teach rabeprazole as a well known benzimidazole. Gilis *et al.* is relied upon for the teaching that omeprazole, rabeprazole, and lansoprazole are all well known proton pump inhibitors (c 5, l 15-18). One of ordinary skill in the art would have used any well known proton pump inhibitor in the composition taught by Depui *et al.*, as the drugs are all from the same family. The expected result would be a successful pharmaceutical formulation, regardless of which proton pump inhibitor is used.

Additionally, Depui *et al.* in view of Gilis *et al.* does not specifically teach sodium hydroxide or potassium hydroxide. However, it is the position of the examiner that based on the teachings of Depui *et al.* to include an alkaline agent, one of ordinary skill in the art would look to any well known alkaline agent. Absent a showing of criticality, there is no reason to believe that one alkaline agent would behave any differently than another. Therefore, one of ordinary skill in the art would have been motivated to use any alkaline agent in the teachings of Depui *et al.* with the expected result being a successful formulation of a benzimidazole. Therefore, this invention as a whole would

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have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 20, and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui *et al.* in view of Gilis *et al.* as applied above, and further in view of US Patent 5,708,017 to Dave *et al.*. Depui *et al.* in view of Gilis *et al.* are described above as teaching a formulation comprising a benzimidazole, an alkaline agent, or an excipient such as HPC or crospovidone, an intermediate coating, an enteric coating and optional additional coatings. Depui *et al.* in view of Gilis *et al.* do not teach that the composition have a moisture resistant coating. Dave *et al.* teach of an oral pharmaceutical composition containing a proton pump inhibitor. Further, Dave *et al.* teach the proton pump inhibitors are known in the pharmaceutical art to be very acid labile and therefore, must be enteric coated. Dave *et al.* also teach that this enteric coating causes a great problem with moisture sensitivity. It is the position of the examiner that one of ordinary skill in the art would have been motivated to make one of the additional coatings allowed in the Depui composition a moisture resistant coating based on the teachings of Dave *et al.*. The expected result would be a successful enteric coated formulation which is resistant to moisture. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been considered but are not found to be persuasive. Applicant's argue that the examiner's original rejection was based on applicant's originally filed claims. However, in light of applicant's amendments to the claims, the examiner has issued the above, slightly varied rejections.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-

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4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

aep
November 2, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600